

Docket No.: 2026-4003US3

Applicants

Waldmann, T.

Group Art Unit: 1642

Serial No.

08/478,748

Filed

June 07, 1995

For

METHOD FOR TREATING MALIGNANCY AND AUTOIMMUNE

DISORDERS IN HUMANS USING ANTI-TAC ANTIBODIES

## DECLARATION

I, Dr. Thomas Waldmann, hereby declare and say that:

- I have read and understood application 08/478,748, including the claims; 1.
- I am the inventor of the subject matter claimed in the above-identified for 2.

patent;

I did not publish or publicly disclose the details for the method of treating 3. . patients afflicted with a disease associated with Tac-positive cells on or before June 7, 1995. In particular, prior to June 7, 1995, I did not publish or publicly disclose a method of treating such patients with a dose comprising 5-15 mCi 90Y-conjugated anti-Tac in a total amount of 2-20 mg anti-Tac, wherein the dose is 2 mg total anti-Tac if said patient has sIL-2R levels of less than 2,000 units/ml, the dose is 5 mg total anti-Tac if said patient has sIL-2R levels of 2,000 - 10,000 units/ml, the dose is 10 mg of total anti-Tac if the patient has sIL-2R levels of 10,000 - 50,000 units/ml, and the dose is 20 mg of total anti-Tac if said patient has sIL-2R levels of greater that 50,000 units/ml; and administering said dosage to said patient to eliminate disease-associated Tac-positive cells.

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4. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Dated: March 22 1999

Dr. Thomas Waldmann